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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,522	09/22/2003	Andre Stamm	107664.115 US13	5813

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

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05/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,522	STAMM ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,13,14,16,18-20,25-33,36 and 38-40* is/are pending in the application.

4a) Of the above claim(s) *6,7,13,14,25-33,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,18-20,36 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/665,519.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, Applicant's Arguments/Remarks and the Information Disclosure Statement (IDS), all filed 3/5/07 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of the amendment to the claims: (1) The 35 U.S.C. §102(b) rejection of claims 1, 8 and 34 over Curtet *et al.* (US 4,895,726) has been withdrawn, since Applicant has cancelled the rejected claims.

Claims 6, 7, 13, 14, 18-20, 25-33, 36 and 38-40 are pending in this action. Claim 16 has been amended. New claim 40 has been added. Claims 1-5, 8-12, 15, 17, 21-24, 34, 35 and 37 have been cancelled. Claims 6, 7, 13, 14, 25-33, 38 and 39 have previously been withdrawn. Claims 16, 18-20, 36 and 40 stand rejected.

Response to Amendment – New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 40 has been added, which recites that "*the daily dose is 160 mg or less*". This amendment constitutes new matter into the claims. The Examiner fails to find support in the instant specification or the originally disclosed claims for the claim limitation "*160 mg or less*" as now claimed. It is noted that the instant specification discloses fenofibrate in dosages of 100 mg and 300 mg (see page 1, line 25). However, support cannot be found for the current claim language of "160 mg or less". Examiner requests clarification as to where support can be found for the newly added claim language of "160 mg or less".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 18-20, 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtet *et al.* (U.S. Patent No. 4,895,726) in view of Kerč *et al.* (U.S. Patent No. 6,042,847).

The instant invention is drawn to an orally administrable immediate release fenofibrate tablet, wherein the required daily dose is lower than 200 mg.

Curtet *et al.* ('726) teach a fenofibrate composition having improved bioavailability, whereby the recommended amount of fenofibrate is about 200 mg per therapeutic unit. The fenofibrate composition can be administered only once daily (column 1, lines 22-27; 50-51). The fenofibrate composition comprises fenofibrate granules in combination with a solid surfactant, wherein the fenofibrate and solid surfactant have been co-micronized; a hydrosoluble carrier and

a hydrophilic polymer, wherein the fenofibrate/solid surfactant mixture granules have a mean particle size of less than 15 microns (see entire reference, particularly, column 1, lines 1-68); (col. 2, lines 1-68); examples and claims. Curtet *et al.* teach polyvinylpyrrolidone as the hydrophilic polymer employed. The hydrosoluble carrier taught can be lactose (col. 2, lines 1-12). The surfactant is selected from solid surfactants and may be an alkali metal sulfate of lauryl alcohol, for example, sodium lauryl sulfate (aka- sodium dodecyl-sulfate), which is the preferred surfactant, provided in a recommended amount of between 0.5% and 7% (col. 1, lines 52-58). Additional excipients include magnesium stearate (lubricant) and starch (disintegrant) (col. 2, lines 1-4).

The mean particle size of the fenofibrate is less than 15 microns, preferably less than 10 microns and particularly preferably less than 5 microns (col. 1, lines 50-66). The recommended amount will be between 0.5% and 7% by weight, relative to the total weight of the formulation. The weight ratio surfactant/fenofibrate will be between about 0.75/100 and 10.5/100 (col. 1, lines 52-60).

Curtet *et al.* teach various dissolution rates using a rotating-vane apparatus, wherein the dissolution medium comprises water and 0.1M sodium lauryl-sulfate (col. 3, lines 34-68 through col. 4, lines 1-63). The values and curve obtained after 20 minutes are plotted in Fig. 1. Additionally, Curtet *et al.* teach comparison results of T 50%, i.e., the time required for 50% of the fenofibrate to dissolve (col. 3, lines 52-60).

Curtet *et al.* do not teach the instant claimed percentages of drug but do teach effective amounts of fenofibrate, whereby the fenofibrate is present in an amount of 200 mg per therapeutic unit. Moreover, the Examiner points out that generally, differences in concentration

will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, the prior art teaches the use of the same drug (fenofibrate), employed once a day and used in similar amounts to achieve enhanced bioavailability of the drug.

With regards to Applicant's limitation of a daily dose of "160 mg or less" of Claim 40, it is the position of the Examiner that the 'about 200 mg' disclosed by Curtet would read on this limitation. Moreover, suitable dosage amounts can be determined by one skilled in the art through manipulative experimentation to obtain optimal results. No unexpected results accrue form the claimed dosage amounts.

Curtet *et al.* teach that the fenofibrate composition can be presented in the form of capsules. Curtet *et al.* do not teach that their granular fenofibrate composition is in the form of a *tablet.* It is familiar to one of ordinary skill in the art that such pharmaceutical compositions can be contained in various dosage forms, such as capsules, tablets, granules and the like. Such skill is also evident from the reference of Kerc *et al.* (see below).

Kerč *et al.* ('847) teach a three-phase fenofibrate pharmaceutical formulation for daily peroral application, wherein the composition can be in the form of tablets or capsules (see reference column 1, lines 18-22); (col. 4, line 34). Kerč *et al.* teach that the granulate of an active ingredient, the water-soluble polymer polyvinylpyrrolidone, cellulose ethers and other ingredients suitable for the preparation of solid pharmaceutical forms has good compressibility,

so prepared tablets are firm, have low brittleness and make possible controlled release of active ingredient (col. 8, lines 54-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the fenofibrate formulations made by compression of granules to form tablets, such as taught by Kerč *et al.* within the fenofibrate compositions of Curtet *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Kerč *et al.* explicitly teach a fenofibrate pharmaceutical composition that can be in suitable forms, such as tablets and teach that the tablets have good compressibility, are less brittle and exhibit firmness. The expected result would be a fenofibrate tablet formulation having improved bioavailability for the beneficial treatment of high cholesterol conditions.

Response to Arguments

Applicant's arguments filed 03/05/07 have been fully considered and were found partially persuasive.

Rejection under 35 U.S.C. 102(b) over Curtet ('726):

Applicant argued, "claims 1, 8 and 34 have been cancelled without prejudice, rendering the rejection moot".

Applicant's arguments were persuasive, in view of the cancellation of the effected claims. Accordingly, the 102(b) rejection has been withdrawn.

Rejection under 35 U.S.C. 103(a) over Curtet ('726) in view of Kerč *et al.* ('847):

Applicant argued, "Neither Curtet nor Kerc disclose the claimed fenofibrate tablet, with an immediate release formulation, where the required daily dosage is lower than 200 mg. Curtet discloses a daily dosage of 200 mg (column 1, lines 50-51, and column 4, lines 34-35). Curtet compares the 200 mg formulation to the standard 300 mg formulation, and shows that the 200 mg dosage form is bioequivalent to the 300 mg dosage form. Hence, Curtet fails to disclose a daily dosage (i) in the form of a tablet and (2) where the dose is lower than 200 mg. Applicants have shown in Example 2 and Figure 1 of the application that the claimed invention has an unexpectedly superior dissolution profile compared to Lipanthyl® 200M, as described by Curtet.

Kerc does not cure the deficiencies of Curtet. Kerc does not provide any motivation or suggestion to modify the dosage form of Curtet to arrive at the claimed tablet. This is particularly the case since Curtet teaches relatively fast release fenofibrate compositions when compared to the sustained release compositions described by Kerc. Kerc teaches away from the claimed invention because Kerc teaches a three-phase pharmaceutical formulation with controlled release properties. The invention, by providing an immediate release tablet with a dosage of less than 200 mg thus provides the further advantage that the inter-patient variation is reduced. A reduced inter-patient variation is a showing that a lesser amount of drug is needed".

Applicant's arguments have been considered, but were not persuasive. Applicant's argument that "Curtet do not disclose a fenofibrate tablet, with an immediate release formulation, with a daily dosage lower than 200 mg" was not persuasive since Curtet explicitly teach a fenofibrate composition having improved bioavailability, whereby the recommended amount of fenofibrate is about 200 mg per therapeutic unit and teaches that the fenofibrate composition can be administered only once daily (see column 1, lines 22-27; 50-51). The "*about* 200 mg" disclosed by Curtet would clearly read on Applicant's limitation of a daily dose 'lower than 200 mg' as claimed. Furthermore the 'about 200 mg' disclosed by Curtet would read on Applicant's limitation of a daily dose of "160 mg or less" as now presented in Claim 40. It is the position of the Examiner that Applicant has not established any patentable distinction, which accrues from the claimed dosage of fenofibrate being lower than 200 mg, since the prior art explicitly teaches a fenofibrate formulation whereby the recommended daily dosage is about 200 mg. Applicant's

arguments that the "instant invention has an unexpectedly superior profile compared to Lipanthyl® 200M" was not persuasive since Applicant's arguments do not establish the scope of claims being presented. The claims, as now introduced, do not encompass any requirement of a specific dissolution profile. With regards to the amounts of fenofibrate claimed in instant claims 18 & 19, the Examiner notes that suitable amounts can be determined by one skilled in the art through routine experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art.

Applicant's argument that "Kerc does not cure the deficiencies of Curtet since Kerc teaches sustained release compositions" was not persuasive, since as admitted by Applicant, Curtet teaches relatively fast release formulations and thus, meets the requirement of immediate release claimed by Applicant. Moreover, the secondary reference of Kerc was relied upon solely for the teaching of fenofibrate compositions in the form of a tablet and thus, fully resolves the deficiency of Curtet. It is not necessary that the secondary reference (Kerc) also teach fast release, since the primary reference (Curtet) initially teaches a fenofibrate formulation that can be fast release.

Applicant's argument that "by providing an immediate release tablet with a dosage less than 200 mg provides the advantage of reducing inter-patient variation" was not persuasive since the prior art explicitly teaches fenofibrate formulations having a daily dosage of about 200 mg, which clearly meets the claimed limitation of 'lower than 200 mg' claimed. Thus, the prior art formulations would also be capable of reducing inter-patient variation since similar dosage amounts as instantly claimed are disclosed. The claims, at present, remain generic enough to read on the explicit reference teachings delineated above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

May 18, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER

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